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In Re: Patent Term Extension
Application for
U.S. Patent No. Re. 34,353

NOTICE OF FINAL DETERMINATION

An application for extension of the patent term of U.S. Patent No. Re. 34,353 under 35 U.S.C. § 156 was filed in the United States Patent and Trademark Office on February 20, 1996. Extension is sought based upon the premarket review under § 510(k) of the Federal Food, Drug, and Cosmetic Act (FFDCA) of a medical device known by the tradename SENSOR PAD®. A determination has been made that U.S. Patent No. Re. 34,353 is NOT eligible for patent term extension under 35 U.S.C. § 156 based upon the regulatory review period of SENSOR PAD®.

A single request for reconsideration of this FINAL DETERMINATION OF INELIGIBILITY may be made if filed by the applicant within TWO MONTHS of the mailing date of this letter. The period for response may be extended pursuant to 37 C.F.R. 1.136. See 37 C.F.R. 1.750. A failure to respond to this letter will result in the application papers being placed into the patent file with no further action taken on the application for patent term extension.

Section 156 of Title 35 permits the term of a patent claiming a medical device which was subject to a "regulatory review period" to be extended for a period of time equal to a calculated portion of the regulatory review period which occurred after the patent was issued. Section 156(a) sets forth the requirements for a patent to be eligible for patent term extension. Among those requirements, § 156(a)(4) requires that the product has been subject to a regulatory review period before its commercial marketing or use.

For the purposes of the statute, the term "regulatory review period" is defined in § 156(g). For a medical device, § 156(g)(3)(B) provides:

> (3)(B) The regulatory review period for a medical device is the sum of -
> (i) the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and
> (i) the period beginning on the date an application was originally submitted with respect to the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

The reference to section 515(f) is a reference to section 515 of the FFDCA. See 35 U.S.C. § 156(f)(4).

The starting point for statutory interpretation is the plain language of the statute. The statute itself must be regarded as conclusive of the meaning absent a clearly contrary legislative intent. Burlington Northern R.R. v. Oklahoma Tax Comm'n, 481 U.S. 454, 461 (1987); Ethicon v. Quigg, 849 F.2d 1422, 7 USPQ2d 1152 (Fed. Cir. 1988). See also, Glaxo Operations UK Ltd. v. Quigg, 894 F.2d 392, 395, 13 USPQ2d 1628, 1630 (Fed. Cir. 1990)(absent a "clearly expressed legislative intention to the contrary," the plain meaning of a statute "must ordinarily be regarded as conclusive").

Under the terms of § 156(a)(4) and § 156(g)(3)(B), the regulatory review of a medical device is limited to a regulatory review which is conducted under section 515 of the FFDCA to the exclusion of regulatory review conducted under section 510(k) of the FFDCA. Accordingly, the regulatory review period for SENSOR PAD® under section 510(k) is not a "regulatory review period" which gives rise to eligibility for patent term extension under 35 U.S.C. 156. In re Nitinol Medical Technologies Inc. , 17 USPQ2d 1492 (Pat. Policy and Programs Admin. 1990).

DECISION

Under the circumstances of this application, for the reasons set forth above, it is held that U.S. Patent No. Re. 34,353 is not eligible for extension of the patent term under 35 U.S.C. § 156. SENSOR PAD® has not been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(a)(4) as defined in 35 U.S.C. § 156(g)(3). Accordingly, the application for extension of the patent term is dismissed.

Any correspondence with respect to this matter should be addressed as follows:

By mail:	Assistant Commissioner for Patents Box Patent Ext. Washington, D.C. 20231
By FAX:	(703) 308-6916 Attn: Special Program Law Office
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Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin Tyson
Legal Advisor
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Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
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RE: SENSOR PAD®
FDA Docket No.: 97E-0069